

REMARKS

The examiner has noted that PCT/FI02/00234 filed 3/21/2002 has not been received. The present application is a continuation-in-part of PCT/FI02/00234 (and not a national stage filing). Therefore, because the present application is a CIP, applicants are not required to submit a copy of PCT/FI02/00234. The examiner can easily download a copy of the parent application.

Claims 1-6 and 11 were objected to because of various informalities. The claims have been amended above to address the examiner's concerns.

Claims 1-2 and 4-6 were rejected under 35 U.S.C. §103(a) as being unpatentable over Campbell et al. (US 6,370,426) in view of Malicki et al. (US 4,918,375) and Zhao (US 5,833,686). Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Campbell et al. (US 6,370,426) in view of Malicki et al. (US 4,918,375), Zhao (US 5,833,686), and Sherwin (US 4,640,290). Claims 7-10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Campbell et al. (US 6,370,426) in view of Amerena (US 4,860,753) and Zhao (US 5,833,686). Claim 11 was rejected under 35 U.S.C. §103(a) as being unpatentable over Malicki et al. (US 4,918,375) in view of Amerena (US 4,860,753) or Campbell (US 6,370,426). The examiner is requested to reconsider these rejections.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Applicants submit that none of the documents, alone or combined together, specify the disclosed requirements for the probe dimensions and measuring frequencies as specified in claims 1, 7 and 11 in this application. The probe dimension has an influence on the measuring depth as described in the specification, and also the used frequency of electromagnetic field effects on the measuring depth of the method.

Please note, that the methods described in Campbell and Amerena can only be used for skin measurements of moisture of the skin surface, and not for skin measurements of deeper structures of the skin. When using the method described in Malicki, it is possible to measure deeper, but there are oblong dagger-like electrodes installed inside the material.

First, applicants wish to define more specifically what edema means. See page 1 lines 3-14 of the specification of the application. In general edema means accumulation of extra water in tissue. Edema refers to a pathologic accumulation of fluid and it also always contains water.

Applicants have amended claim 1 to recite, *inter alia*, "the distance between two electrodes of the probe being large enough in order for the electronic field to penetrate up to the subcutaneous fat tissue, and the said distance is about 2-10 mm".

Campbell et al. discloses a method and an apparatus for measuring relative hydration of a substrate. The force applied to the substrate and the temperature of the substrate during the measurements is used to ensure proper results of relative hydration. Campbell teaches that the invention can

also be used to measure skin. Through the whole document, a term of relative hydration is used. It is measured in the sense of impedance, and to be more specific, capacitive reactance is measured. However Campbell does not disclose anything about the measuring depth or the dimension of the probe in the document. As mentioned above, the probe dimension has an influence on the measuring depth. Another essential difference between the applicants' claimed invention and this patent is that Campbell does not describe anything about the used frequency of the electromagnetic field, in addition to the probe dimensions, which also effects the measuring depth of the method.

The examiner argues that Campbell discloses a method for measuring edema. Applicants submit that this is not true, and it is only the examiner's opinion, as the examiner has mischaracterized Campbell. Applicants disagree with the examiner because Campbell does not mention edema at all in the document. Figure 1 (or col. 4, lines 49-65) is not persuasive since Campbell does not teach a measuring depth of the method. Moreover, the concept of skin hydration refers just to superficial moisture content of the skin. Superficial means the uppermost 20-50 micrometers of skin. Applicants also submit that Campbell is silent to the frequency used and the distance between the electrodes. However, these features are essential parts of applicants' claimed invention (see claims 1, 7 and 11).

The examiner also admits that Campbell et al. does not disclose the capacitance of the probe as proportional to the

electric constant of the skin and subcutaneous fat issue and proportional to the water content of the skin.

There are several essential features of applicants' claimed invention, which Campbell et al. does not disclose. Therefore it is difficult to understand how this patent is cited in connection with applicants' claimed invention.

Malicki et al. discloses a reflectrometric moisture meter for capillary-porous materials, especially for the soil. As mentioned above, the measuring is made by using oblong dagger-like electrodes installed inside the material. As mentioned in the title of the patent, this meter is for the measuring of soil. There is no mention or description of measuring of the edema or measuring the skin. Applicants further submit that skin is not a capillary-porous material as meant in patent of Malicki. Skin is not on the list of materials intended to be measured, as presented by Malicki.

Applicants wish to mention that the claims include specified dimensions to measure edema and deeper layers of the skin and subcutaneous fat (claims 1, 7 and 11).

Zhao is merely used by the examiner to teach the desired frequency range for use on skin. However, Zhao does teach the frequency range. Applicants do not understand how the purpose and the device described in the patent of Zhao can be presented as a document cited against the present invention.

Zhao discloses an apparatus using frequency of 50 MHz. However, in spite of that, Zhao does not mention anything about measuring edema. Applicants disagree that Zhao teaches

anything of penetration depth using the electromagnetic field of 50 MHz. Hence the argument that Zhao teaches that 50 MHz will penetrate the skin with some quantitative terms is not true. Zhao describes that the ultra-high-frequency cosmetic apparatus is suitable for use in medical beauty treatment without any scarring and the restoration period after using the apparatus (see very short brief description in the abstract). All these descriptive facts mean that the effective depth of the treatment must be very superficial. Applicants also disclose that if the frequency is in the range of 20-50 MHz, the measuring depth is superficial and only the uppermost layers of the skin are measured.

Applicants doubt that it is not obvious to one of ordinary skill in the art at the time of the invention that subcutaneous fat tissue has a low dielectric constant. It is even more complicated since the value of dielectric constant varies with the measuring frequency. It means that the dielectric constant has a different value at different frequencies. This phenomena is typical for biological tissue and it is called dispersion. Also, the value of the dielectric constant is proportional to water especially at a very-high-frequency range. At a lower frequency, many other structures of tissue (like cell membrane) have an effect on the value of dielectric constant.

Applicants also submit that it is not valid to compare the skin to a capillary-porous material as made by the Examiner. If this refers somehow to sweat glands or hair follicles of skin, applicants note that they cover only 0.1-1 % of the total skin surface. Instead, the skin surface is a main

barrier between the outer environment and the living tissue. The uppermost part of skin, called stratum corneum, forms a dead keratinised horny layer. Stratum corneum layered cells contain keratins and lipids. This lipid matrix is for example a main barrier to the penetration of drugs through the skin. Hence applicants conclude that skin cannot be considered as a capillary-porous material at all.

Moreover, skin is a vital organ and Malicki discloses a method to measure soil that contains many more minerals than living organs. Malicki teaches that the apparatus measuring water content can be applied for any capillary-porous material which allows introduction of the probe in a non-destructive way (see col. 8, lines 38-40). Malicki, moreover, gives examples of those kinds of materials: soil, grain, hay, flour, wood, sand etc. (see col. 8, lines 40-44). None of these examples are living animal tissue and to be more specific skin or skin like material.

Applicants submit that there appears to be a strange comparison between treating skin and measuring skin. Zhao does not teach or suggest anything about measuring or even treating skin, particularly edema. Applicants do not see why skin water content should be treated.

Dependent claim 3 claims a method wherein "for the measurement the probe is secured on the skin by an attachment, such as strap-like attachment, for a long time, for instance hours or days, in which case the edema can be monitored continuously". Sherwin teaches using straps as an effective method of attaching a probe to the body of a patient. This appears to

be true, however, Sherwin does not describe a method as described in independent claim 1 of this application.

The features of claim 1 are not disclosed or suggested in the art of record. Therefore, claim 1 is patentable and should be allowed.

Though dependent claims 2 and 4-6 contain their own allowable subject matter, these claims should at least be allowable due to their dependence from allowable claim 1. However, to expedite prosecution at this time, no further comment will be made.

Claim 7 claims a device for measuring tissue edema, which device includes an electromagnetic probe in order to be placed on the skin during the measurement, wherein a capacitance of the probe is proportional to a dielectric constant of the skin and subcutaneous fat tissue, which is further proportional to a water content of the skin, a high frequency unit for measuring the capacitance of the electromagnetic probe at a high frequency, approximately 20-500 MHz, a unit for calculating measured values and the tissue edema, and a distance between two electrodes of the probe being large enough in order for the electronic field to penetrate up to the subcutaneous fat tissue, and the said distance is about 2-10 mm.

Similar to the arguments presented above with respect to claim 1, Campbell does not disclose anything about measuring edema, or the frequency used, or the distance between the two electrodes of the probe.

The examiner argues that Amerena discloses a probe used to measure the water content of skin comprising two concentric electrodes spaced in the range of 2-10 mm as an effective device for such purpose. Applicants disagree and submit that this document should not be relevant.

Amerena discloses a probe to measure skin surface moisture content using a capacitive method. Amerena even tells that the probe measures only the skin surface (see abstract, line 4). Regarding the probe dimensions, the probe described by Amerena has a smaller dimension than in the present invention. Namely, Amerena discloses that the probe end (24) has a diameter of about one centimetre (see col. 2, lines 42-45). Now this known width can be compared to the figures 2 and 3. Hence it can be easily measured by a ruler that the distance between inner (28) and outer (26) electrodes must be below 2 mm (Fig 2). In the present invitation, however, the distance between the two electrodes is from about 2 to 10 mm (as claimed in claims 1, 7, and 11). Using this kind of larger probe and frequency of 20-500 MHz, the water content of deeper structures can also be measured (claims 1, 7, 11).

Similar to the arguments presented above with respect to claim 1, Zhao teaches to use a frequency of about 50 MHz. However, Zhao does not teach other features of the invention described in this application. Applicants also mention again that Zhao does not teach or suggest anything about measuring edema.

The features of claim 7 are not disclosed or suggested in the art of record. Therefore, claim 7 is patentable and should be allowed.

Though dependent claims 8-10 contain their own allowable subject matter, these claims should at least be allowable due to their dependence from allowable claim 7. However, to expedite prosecution at this time, no further comment will be made.

Applicants have amended claim 11 to recite, *inter alia*, "placing an electromagnetic probe on the skin, wherein a distance between two electrodes of the probe is about 2-10 mm". Similar to the arguments presented above with respect to claims 1 and 7, the features of claim 11 are not disclosed or suggested in the art of record. The method and purpose of applicants invention described in the patent of Malicki are quite different than described here. The features of claim 11 are not disclosed or suggested in the art of record. Therefore, claim 11 is patentable and should be allowed.

Applicants submit once more that none of the present documents describe the invention described in this application. Applicants have attacked the references individually because all these documents are so different (and are therefore non-analogous art). Applicants submit that the examiner has combined the features described in these documents arbitrary and purposefully. A person skilled in the art can not take one specific feature of one cited document, second specific feature of the second cited document, third specific feature from the third document and argue that this combination is obvious for a person skilled in the art.

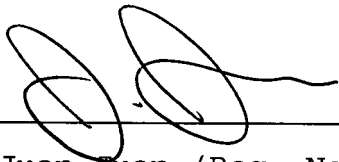
Additionally, applicants repeat that proper motivation is lacking for said combinations. The examiner further argues

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that applicants have also disclosed that at least certain aspects of the inventions are known in the art. Of course the applicants use known electronic components in the device, but the method and device as such are new and innovative.

For all of the foregoing reasons, it is respectfully submitted that all of the claims now present in the application are clearly novel and patentable over the prior art of record. Accordingly, favorable reconsideration and allowance is respectfully requested. Should any unresolved issue remain, the examiner is invited to call applicants' attorney at the telephone number indicated below.

Respectfully submitted,



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